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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,408	07/25/2003	Manikkam Suthanthiran	955-10 P/CON/DIV	2823

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,408	SUTHANTHIRAN ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4, 14, drawn to a method for reducing or preventing formation or metastasis of a neoplasm in a mammal comprising treating the mammal with an effective amount of an angiotensin II inhibitor wherein the inhibitor is an *angiotensin converting enzyme* (ACE) inhibitor, classified in class 424, subclass 184.1; class 514, subclass 1.

II. Claims 1-3, 5, 12, 14, drawn to a method for reducing or preventing formation or metastasis of a neoplasm in a mammal comprising treating the mammal with an effective amount of an angiotensin II inhibitor wherein the inhibitor comprises an *anti-angiotensin II antibody*, classified in class 424, subclass 130.1.

III. Claims 1-2, 6, 14, drawn to a method for reducing or preventing formation or metastasis of a neoplasm in a mammal comprising treating the mammal with an effective amount of an angiotensin II inhibitor wherein the inhibitor comprises an *anti-angiotensin I antibody*, classified in class 424, subclass 130.1.

IV. Claims 1-2, 7, 14, drawn to a method for reducing or preventing formation or metastasis of a neoplasm in a mammal comprising treating the mammal with an effective amount of an angiotensin II inhibitor wherein the inhibitor comprises an *anti-angiotensinogen antibody*, classified in class 424, subclass 130.1.

V. Claims 1-3, 8, 14, drawn to a method for reducing or preventing formation or metastasis of a neoplasm in a mammal comprising treating the mammal with an effective amount of an angiotensin II inhibitor wherein the inhibitor is a *protein or peptide*, classified in class 424, subclass 184.1.

VI. Claims 1-2, 9-10, 14, drawn to a method for reducing or preventing formation or metastasis of a neoplasm in a mammal comprising treating the mammal with an effective amount of an angiotensin II inhibitor wherein the angiotensin II inhibitor is a *renin inhibitor*, classified in class 530, subclass 860.

VII. Claims 1-2, 11, 14, drawn to a method for reducing or preventing formation or metastasis of a neoplasm in a mammal comprising treating the mammal with an effective amount of an angiotensin II inhibitor wherein the inhibitor *blocks expression of angiotensinogen*, classified in class 514, subclass 44.

VIII. Claims 1-2, 13-14, drawn to a method for reducing or preventing formation or metastasis of a neoplasm in a mammal comprising treating the mammal with an

effective amount of an angiotensin II inhibitor wherein the inhibitor is a small molecule, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-VIII represent materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. For example, Group I is broadly drawn to administering ACE inhibitors which could include any number of distinct molecules with anti-ACE activity. Groups II-IV are drawn to administering distinctly different antibodies. Group II administers an anti-angiotensin II antibody. Group III administers an anti-angiotensin I antibody, and Group IV requires administration of an anti-angiotensinogen antibody. The administration of each antibody represents an independent group because the proteins to which the antibodies bind comprise different amino acids with different binding regions or epitopes. Further, a search for one antibody in the method would not necessarily include a search for the other antibody. Further, Group V is drawn to administering proteins or peptides that function to inhibit angiotensin II. While the inventions of Group V and Group II-IV are polypeptides, in this instance the polypeptides of Group V represent various proposed inhibitors of angiotensin II, whereas the polypeptides of Groups II-IV encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDR) that function to bind an epitope. Thus the polypeptides of Group V and the antibodies of Group II-IV are

structurally distinct molecules; any relationship between a polypeptide of Group IV and an antibody of Group II, III or IV is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. Group VI is drawn to administering a renin inhibitor which is functionally distinct and classified separately from the other groups; hence, a search for renin inhibitors would not necessarily include a search for the other inhibitors. Groups VII and VIII are further distinct, each from the other groups, in that Group VII functions to block the expression of angiotensinogen which encompasses the administration of nucleic acids to mammals. Hence, Group VII reads on gene therapy. Such therapy differs from the other groups in method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Lastly, Group VIII is drawn to the administration of "small molecule" inhibitors. This includes (see specification) a genus of molecules such as organic compounds, inorganic compounds, organometallic compounds, salts of organic and organometallic compounds, saccharides, amino acids, and nucleotides. Small molecules further include molecules that would otherwise be considered biological molecules, except their molecular weight is not greater than 450. Thus, small molecules may be lipids, oligosaccharides, oligopeptides, and oligonucleotides, and their derivatives, having a molecular weight of 450 or less. Administration of any and all such small molecules would not necessarily include the administration of the other compounds. Further, searching all of the inventions of Groups I-VIII would impose a serious search burden because it would require extensive searching of different, unrelated compounds in the literature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

A telephone call was made to Edna Gergel, Ph.D. on November 16, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
November 16, 2005

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER